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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,343	11/23/2001	Karen Akinsanya	033236/0114	6930

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,343	AKINSANYA ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendments (filed 23 November 2001, 20 June 2003 and 28 October 2004) have been entered in full.

Applicant's species election with traverse, wherein Xaa1 is His, Xaa2 is Trp and Xaa3 is Tyr (i.e. SEQ ID NO:6) in the reply filed on 28 October 2004 is acknowledged. The traversal is on the grounds that the international examination report does not formally raise a lack of unity objection. Applicant argues that according to the PCT Handbook, Section 33.35 (Exhibit A), a designated/elected office should not raise an objection as to lack of unity (Rule 13 PCT) when the International Examination Authority has found that the claims comply with this requirement. Applicant argues that all peptides with SEQ ID NO:7 share the same inventive concept and that SEQ ID NO:7 defines a very small number of peptides and all of the defined peptides are active.

Applicant's arguments have been fully considered but are not found persuasive. MPEP 1893.03 (d) states if the Examiner finds that a national stage application lacks unity of invention under 1.475, the Examiner may in an Office action require the Applicant in the response to that action to elect the invention to which the claims shall be restricted. The Examiner requested a species election because the claims lacked the same or corresponding special technical features. The claims comprise various combinations of amino acids. The SEQ ID NOs are distinct sequences because they are composed of diverse chemical compounds, different coding regions and/or impart structural and functional differences. As was stated in the Restriction/Election

Requirement, upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species.

The requirement is still deemed proper and is therefore made FINAL. Applicant timely traversed the restriction (election) requirement in the reply filed on 28 October 2004. Claims 1-12 (and species election SEQ ID NO:6) are under examination.

Information Disclosure Statement

The information disclosure statement (IDS) filed 23 November 2001 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. At this time, the Examiner will not consider U.S. Patent 4,721,755. The IDS has Folkers *et al.* listed as the inventor for U.S. Patent 4,721,755. Maatman is actually the inventor for U.S. Patent 4,721,755. Thus, it is unclear if the mistake is the inventor or the patent number. Clarification is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. The instant claims are drawn to a pharmaceutical composition for the treatment of osteoporosis and other disorders of bone metabolism or for accelerating bone growth or repair wherein the composition comprises pyroGlu-His-Trp-Ser-Xaa1-Gly-Xaa2-Xaa3-Pro-Gly-NH2 and a method of treatment of an individual suffering from osteoporosis or another disorder of bone growth, or at risk of so suffering, comprising the administration to said individual a pharmaceutical composition comprising pyroGlu-His-Trp-Ser-Xaa1-Gly-Xaa2-Xaa3-Pro-Gly-NH2.

The subject matter sought to be patented as defined by the claims is not supported by an enabling disclosure because the specification fails to teach how to treat an individual suffering from osteoporosis or any other bone growth disorder with a composition comprising pyroGlu-His-Trp-Ser-Xaa1-Gly-Xaa2-Xaa3-Pro-Gly-NH2 or demonstrate said composition has the activity of accelerating bone growth or repair. PyroGlu-His-Trp-Ser-Xaa1-Gly-Xaa2-Xaa3-Pro-Gly-NH2 is an analogue of gonadotropin-releasing hormone II (GnRH). The specification fails to teach the use of the instant composition in osteoporosis or bone growth disorder animal models. The specification fails to teach or disclose examples regarding the amount and/or route of administration of this pharmaceutical composition for treatment in mammals. The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. Lacking working examples, however is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. In the instant case, the art teaches that GnRH agonist treatment causes *decreases* in bone density.

Please see the references submitted by the Examiner (Smith *et al.,* Journal of Urology and Kazanis *et al.,* Abstract, Clinical Reviews in Bone and Mineral Metabolism). In addition, Paoletti *et al.* (abstract submitted by Applicant) teach that lumbar bone mineral density values decreased significantly after six months of GnRH analogue treatment in women suffering endometriosis. Thus it is unclear, how an individual suffering from osteoporosis or other disorders of bone growth could be treated with the instant composition. There is a great level of unpredictability because the art teaches the opposite effect and the instant disclosure fails to provide sufficient direction or guidance. In light of the art teaching conflicting data and the lack of animal (*in vivo*) models demonstrating increased bone density upon administering pyroGlu-His-Trp-Ser-Xaa1-Gly-Xaa2-Xaa3-Pro-Gly-NH2, the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue.

Due to the large quantity of experimentation necessary to treat a bone growth disorder in an individual comprising administering pyroGlu-His-Trp-Ser-Xaa1-Gly-Xaa2-Xaa3-Pro-Gly-NH2, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the contradictory state of the prior art and the unpredictability of the effects of GnRH on bone density, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-12 are indefinite because a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). The claims recite, "osteoporosis, including age-related osteoporosis and osteoporosis associated with post-menopausal hormone status....". In the present instance, claims 1-12 recites the broad recitation "including" and the claim also recites specific diseases (i.e. primary and secondary hyperparathyroidism, diabetes-related osteoporosis, etc) which is the narrower statement of the range/limitation.

Claims 1-12 are indefinite because of the recitation, "other disorders of bone metabolism". Because the term "other" is open ended, the metes and bounds of the instant claims cannot be determined.

Claims 11 and 12 are indefinite because they provide for the use of a peptide as a therapeutic agent, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11 and 12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Fernald *et al.,* WO 95/12309. The instant claims are drawn to a pharmaceutical composition and a method for preparing a pharmaceutical composition for the treatment of osteoporosis and other disorders of bone metabolism, wherein the composition is pyroGlu-His-Trp-Ser-Xaa1-Gly-Xaa2-Xaa3-Pro-Gly-NH2. Fernald *et al.* teach the amino acid of chicken II gonadotropin-releasing hormone (GnRH). The amino acid sequence of Fernald *et al.* is the same sequence as SEQ ID NO:6 in the instant claims (Fernald *et al.,* page 1, lines 24-38, Figure 1a and Figure 1b). Fernald *et al.* teach pharmaceutical compositions and methods of preparing pharmaceutical compositions comprising SEQ ID NO:6 (page 2, line 30--age 3, line 20 and page 32, line 32-page 33, line 32).

It is noted that the instant claims are directed to a composition. The intended use of the claimed composition is given patentable weight when making a determination of patentability under 35 U.S.C. 102 only when it serves to define a structural requirement. In composition claims, the intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
1/5/05

ELIZABETH KEMMERER
PRIMARY EXAMINER